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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,477	11/21/2003	Lieping Chen	07039-443001	3624

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EXAMINER

OUSPENSKI, ILIA I

ART UNIT	PAPER NUMBER
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1644

MAIL DATE	DELIVERY MODE
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10/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/719,477	Applicant(s) CHEN ET AL.	
	Examiner ILIA OUSPENSKI	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2007 and 20 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19, 21-26 and 28-39 is/are pending in the application.
- 4a) Of the above claim(s) 1-18 and 28-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19, 21-26 and 28-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed on 08/20/2007 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/20/2007 has been entered.

Applicant's amendment and remarks, filed on 05/03/2007, are acknowledged, and have been entered.

Claims 1 – 19, 21 – 26, and 28 – 39 are pending.

Claims 1 – 18 and 32 – 39 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Inventions/Species, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in the reply filed on 05/08/2006.

Claims 19, 21 – 26, and 28 – 31 are under consideration in the instant application.

This Office Action will be in response to applicant's amendment and arguments, filed on 08/20/2007.

The rejections of record can be found in the previous Office Action, mailed on 01/19/2007.

The rejections of record have been withdrawn in view of Applicant's amendment and arguments, except as set forth herein.

It is noted that New Grounds of Rejection are set forth herein.

2. It is noted that Applicant's arguments regarding the rejection of record under 35 USC 112, first paragraph (enablement) rely on evidentiary references provided as Exhibits A – E. These references have been cited of record in the file of the instant application.

3. The following is a quotation of the **second paragraph of 35 U.S.C. 112**.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 25 – 26 and 28 – 31 stand rejected under **35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 25 – 26 and 28 – 31 are indefinite in the recitation of "wherein the level of one or more B7-H1-specific antibodies in the sample correlates with the stage of the disease or pathological condition," because the phrase is vague and indefinite.

Applicant's arguments have been fully considered but have not been found convincing.

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Applicant argues that the skilled artisan can ascertain normal levels of antibody as it pertains to a particular disease or condition.

This is not seen as addressing the ambiguity of the claim language, in particular with respect to the direction of the recited "correlation," i.e. positive or negative, and to the meaning of the "stage" of the disease, i.e. does a higher level of antibody mean a more advanced stage of disease, or a less advanced?

Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended claims. The rejection of record is incorporated by reference herein, as if reiterated in full.

New Grounds of Rejection

5. The following is a quotation of the **first paragraph of 35 U.S.C. 112**:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 19, 21 – 26, and 28 – 31 are rejected under **35 U.S.C. 112, first paragraph**, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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The specification does not enable one of skill in the art to practice the invention as claimed without undue experimentation. Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, limited working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

The specification does not provide a sufficient enabling description of the claimed methods, because it does not provide a sufficient enabling description of how to determine whether the level of recited antibodies in the sample is "elevated."

The specification discloses a working example wherein the levels of anti-B7-H1 autoantibodies in RA patients is compared to that of healthy patients (e.g. Figure 1E). However, this is not seen as sufficient as enabling the skilled artisan to practice the claimed methods as they apply to other autoimmune conditions.

Applicant's arguments at pages 9 – 11 of the Response filed on 05/03/2007 are seen as pertinent to the present rejection. Applicant submits that the present invention is not limited by methods of establishing "normal" values and that any of a number of possible "normal" values can be used in the claimed methods. One of skill in the art would need to determine whether the variability of autoantibody levels between subjects is high or low, and to establish the feasibility of performing the methods of the instant claims.

It is acknowledged that the methods one of skill in the art would use to ascertain how to determine the "elevated" level of autoantibody indicative of disease are routine in the art; however, given the limited guidance the amount of experimentation required appears to be unnecessarily, and improperly, extensive and undue.

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7. Conclusion: no claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, reading "Ilia Ouspenski". The signature is written in a cursive, flowing style with a large initial 'I'.

ILIA OUSPENSKI, Ph.D.

Patent Examiner

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October 6, 2007